IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9360

Bartle, J. October 16, 2014

James P. Holleyhead ("Mr. Holleyhead" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[3] See Settlement Agreement §§ IV.B.1.a. & I.22.

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2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

In April, 2012, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated July 9, 2002, Dr. Dlabal attested in Part II of claimant's Green Form that Mr. Holleyhead had mild aortic regurgitation, congenital aortic valve abnormalities,[4] and surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix B-1, Level III benefits in the amount of $163,326.[6]

In the report of claimant's July 9, 2002 echocardiogram, the reviewing cardiologist, Waenard L. Miller, M.D., F.A.C.C., found that claimant had moderate aortic regurgitation, which he measured at 33%. Under the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal

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4. Under the Settlement Agreement, the presence of congenital aortic valve abnormalities requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)a).

5. Dr. Dlabal also attested that claimant suffered from mild mitral regurgitation, arrhythmias, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In July, 2012, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Wang determined that there was no reasonable medical basis for the attesting physician's representation that Mr. Holleyhead had mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Wang observed that "[t]here was trace aortic regurgitation (JH/LVOTH was 4%) which was confirmed by [transesophageal echocardiogram] on 12/17/09."[7] She explained, "In the study, the JH was measured at [sic] Nyquist limit of 33 cm/s which made [sic] [aortic insufficiency] jet height falsely higher than the actual one."[8]

Based on Dr. Wang's finding, the Trust issued a post-audit determination denying Mr. Holleyhead's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[9]

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7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is defined as a JH/LVOTH ratio of less than 10%.

8. In her attestation, Dr. Wang noted that she "mistakenly wrote" in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue that claimant's aortic regurgitation was 12%.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition

(continued...)

In contest, Mr. Holleyhead argued that it is not the role of the Trust to "second guess" the attesting physician.[10] Claimant also contended that there was a reasonable medical basis for his claim because four cardiologists, including one of the Trust's auditors, Keith B. Churchwell, M.D., agreed that his echocardiogram demonstrated at least mild aortic regurgitation. In support, claimant submitted declarations from Dr. Dlabal and Gerald M. Koppes, M.D. In his declaration, Dr. Dlabal's stated, in pertinent part:

> 5. The [aortic insufficiency] was not trace. Clearly, at least mild [aortic insufficiency] was shown on the study, and there was a reasonable medical basis for a finding of at least mild [aortic insufficiency].
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> 6. While part of the study was taken at a Nyquist limit of 33, the initial part of the study was made at Nyquist limits between 64 and 69, and there was ample clinical data to indicate the nature and severity of the [aortic insufficiency], as set forth above.
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> 7. Further, the jets that I identified were true regurgitant jets, they were not artifacts, they were not "falsely higher than the actual one(s)," and they were

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9. (...continued)
of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Holleyhead's claim.

10. Claimant also included in his contest materials the audit results from claimant's initial Green Form, received by the Trust in May, 2003.

> representative of other jets that were clearly in the mild range.[11]

In his declaration, Dr. Koppes also asserted that claimant's echocardiogram revealed at least mild aortic regurgitation:

> 4. The measured JH/LVOTH was 12 to 15%. Visually the [aortic insufficiency] appeared to be mild rather than trace. The jets were true regurgitant jets, and they were representative of other jets that were also in the mild range.
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> 5. Dr. Wang, the 2nd auditor, felt that the [aortic insufficiency] was less than mild since part of the study was at a Nyquist limit of 33 cm/sec making the jet height "falsely high." The initial part of the study was made at 70 cm/sec. The [aortic insufficiency] visually appeared to be mild at both settings, and the ratio was greater than 10% with either setting. The degree of [aortic insufficiency] will frequently appear different at different angles due to an eccentric [aortic insufficiency] jet, and the 2nd auditor apparently failed to account for this difference. The size of the color jet can appear larger with a lower Nyquist limit, but no artifact or increased color pixels were seen in this study.
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> 6. In my opinion, there was a reasonable medical basis for a finding of mild [aortic insufficiency] in this case.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for Dr. Dlabal's representation

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11. Dr. Dlabal also included a still frame image from claimant's echocardiogram, which purportedly demonstrated a JH/LVOTH ratio of at least 30%.

that Mr. Holleyhead had at least mild aortic regurgitation.

Dr. Wang explained, in pertinent part:

> 10. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had mild aortic regurgitation. There is only trace aortic regurgitation present on the July 9, 2002 echocardiogram of attestation. At the time of audit, I noted that Claimant had only trace aortic regurgitation with a JH/LVOTH ratio of 4%. (While I initially entered 12% in the electronic audit application, I corrected this value when subsequently completing the Attestation forms.)
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> 11. Upon review at Contest, I confirmed that aortic regurgitation on the July 9, 2002 study is only trace. Generally, JH/LVOTH should be measured at the parasternal long and short axis because of better axial resolution. Normally, the width of an aortic regurgitation jet is greater from an apical view compared with a parasternal view. This is because the jet's width recorded from a parasternal projection depends on axial resolution, whereas the same dimension recorded apically will rely more on lateral resolution, resulting in the appearance of a wider jet. On the July 9, 2002 echocardiogram, the [aortic insufficiency] jet was not visible at the parasternal long or short axis at aliasing velocity at 60s m/s. The LVOT[H] measured at parasternal long axis was 2.1cm. The [aortic insufficiency] jet may be visualized at 3 and 5 chamber views, where it is trace in severity. In fact, the aortic regurgitation was so minimal that it cannot be detected by [Continuous Wave] Doppler. In summary, the [aortic insufficiency] jet cannot be visualized at parasternal long and short axis views, but it is trace in the 3 and 5 chamber views, therefore, the [aortic insufficiency] is trace. There is no

> reasonable medical basis to conclude that mild mitral regurgitation is present on the July 9, 2002 echocardiogram study.

The Trust then issued a final post-audit determination, again denying Mr. Holleyhead's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On February 1, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9002 (Feb. 1, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 5, 2013, and claimant submitted a sur-reply on April 26, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[12] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's representation that Mr. Holleyhead suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, claimant reasserts the arguments he made during contest. Claimant also argues that, although a portion of the echocardiogram was conducted with a low Nyquist limit, part of the study was conducted with an appropriate Nyquist limit and it is this part of the echocardiogram that reveals at least mild aortic regurgitation.

Claimant further maintains that his physicians adequately contested the findings of the auditing cardiologist and established a reasonable medical basis for a finding of at least mild aortic regurgitation.

Claimant also submitted supplemental declarations from Dr. Dlabal and Dr. Koppes, in which they again opine that the auditing cardiologist is incorrect and that claimant's echocardiogram reveals the presence of at least mild aortic regurgitation. In addition, claimant notes that his physicians properly determined the level of aortic regurgitation in the apical views on the echocardiogram because aortic regurgitation was not well seen in the parasternal views.[13] Finally, claimant asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "'guaranteed' payments if [a claimant's] condition worsened to certain points ...."

The Trust counters that claimant has not established a reasonable medical basis for Dr. Dlabal's representation that Mr. Holleyhead had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. In addition, the Trust contends that it properly applied

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13. In his declaration, Dr. Koppes concedes, "The [parasternal long-axis] view does give better axial (up and down resolution) vs. apical view giving lateral (side by side resolution)." Dr. Koppes also states that "mild [aortic insufficiency] was documented in several views including [parasternal long-axis view]." In his declaration, Dr. Dlabal states, "I agree that [aortic insufficiency] was not as well seen in the [parasternal] views as in the [apical] views, and for that reason selected the [apical] views for diagnostic evaluation."

the reasonable medical basis standard. Finally, the Trust asserts that the Settlement Agreement does not "guarantee" claimants supplemental Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Mr. Holleyhead had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Vigilante explained, in pertinent part:

> I reviewed the Tape and DVD of the Claimant's echocardiogram of July 9, 2002.... This was a fair quality study with the usual echocardiographic views obtained. The Nyquist limit was appropriately set at 71 cm per second in the parasternal long-axis view and 67 cm in the apical views. However, towards the end of the study, the Nyquist limit was inappropriately set at 33 cm per second. This caused a tremendous amount of artifact and excessive color gain. However, it should be noted that this study was interpretable.
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> .... The parasternal long-axis view was available and completely interpretable for evaluation. I digitized the cardiac cycles in the parasternal long-axis view. The LVOTH was 2.0 cm. There was no evidence of aortic regurgitation in the parasternal long-axis view at the appropriate Nyquist limit of 71 cm per second. Only when there was excessive color gain and significant artifact at a Nyquist limit of 33 cm per second in the parasternal long-axis view was trace aortic regurgitation suggested. However, the JH could not be accurately measured at such a low Nyquist limit due to artifact. The aortic valve was also evaluated in the apical three and five chamber views. In these views, only trace aortic regurgitation was obviously present. However, when the available and appropriate parasternal

> long-axis view was reviewed at the appropriate Nyquist limit, no aortic regurgitation was seen. There was no view that was consistent with mild or greater aortic regurgitation in this study. The time frames documented by Dr. Koppes in his Supplemental Declaration regarding the presence of aortic regurgitation in the parasternal long-axis view referred only to that part of the study during which the Nyquist limit was inappropriately set very low at 33 cm per second. An accurate measurement of the JH is not possible at such an inappropriately low Nyquist limit. At a normal Nyquist limit of 70 cm per second, no aortic regurgitation was seen in this view. Time frames documented by Dr. Dlabal in his Declaration refer to the apical five and three chamber views. In these views, there was obviously trace aortic regurgitation. However, as per the Settlement Agreement, the parasternal long-axis view was available and no aortic regurgitation was seen in those cardiac cycles in which a proper Nyquist limit was used.
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> ....
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> [T]here was no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.b. That is, the echocardiogram of attestation demonstrated no aortic regurgitation in the parasternal long-axis view when evaluating the appropriately acquired cardiac cycles. In the other views, it was obvious that there was no worse than trace aortic regurgitation. An echocardiographer could not reasonably conclude that the echocardiographic study of July 9, 2002 demonstrated aortic regurgitation worse than trace aortic insufficiency even taking into account the issue of inter-reader variability.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor failed to apply the reasonable medical basis standard because he did not provide any times or still frame images, and instead "substituted his non-objective"

opinion.[14] Claimant also asserts that the Technical Advisor's finding that the parasternal long-axis view is evaluable was erroneous because, in that view, the Nyquist limit was inappropriately set at 33 cm/sec.[15]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, the declarations from Dr. Dlabal and Dr. Koppes do not provide a reasonable medical basis for finding that Mr. Holleyhead had at least mild mitral regurgitation before the end of the Screening Period. Dr. Wang reviewed claimant's echocardiogram and determined that aortic regurgitant jet was not visible in the parasternal long-axis view during a time when the appropriate

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14. Claimant initially included with his response to the Technical Advisor Report a verified "rebuttal" by Dr. Dlabal. Pursuant to Audit Rule 34, the Special Master determined this rebuttal could not become part of the Show Cause Record. Thereafter, claimant filed "objections" to the decision denying the inclusion of this rebuttal in the Show Cause Record and a motion to have it included. According to claimant, in his rebuttal, Dr. Dlabal disputes the Technical Advisor's finding with respect to the level of aortic regurgitation. Pursuant to Audit Rule 34, there is no procedure by which Dr. Dlabal's supplemental statement can become part of the Show Cause Record. See, e.g., Mem. in Supp. of PTO No. 9041, at 9 n.11 (Apr. 5, 2013); Mem. in Supp. of PTO No. 8402, at 12 n.13 (Feb. 22, 2010). For these reasons, we will overrule claimant's objections and deny his motion.

15. In addition, claimant argues that accepting the technician's JH measurement of 0.6 cm, which Dr. Vigilante does not contest, and Dr. Vigilante's own LVOTH measurement of 2.0 cm results in a JH/LVOTH ratio of 30%, which qualifies as moderate aortic regurgitation. This, however, ignores, Dr. Vigilante's specific statement that "there was no evidence of aortic regurgitation in the parasternal long-axis view."

Nyquist limit was set. Accordingly, she reviewed the apical three- and five-chamber views and determined that the level of claimant's aortic regurgitation was trace.[16] Dr. Wang observed that "the width of an aortic regurgitation jet is greater from an apical view compared with a parasternal view ... because the jet's width recorded from a parasternal projection depends on axial resolution, whereas the same dimension recorded apically will rely more on lateral resolution, resulting in the appearance of a wider jet."

Dr. Dlabal agreed with Dr. Wang that the parasternal long-axis view was unavailable for evaluation of claimant's level of aortic regurgitation, but he stated that her finding of trace aortic regurgitation "cannot be supported by the facts." Instead, Dr. Dlabal opined that "multiple images" demonstrated an aortic insufficiency "equal to or greater than 10%...." Dr. Koppes also agreed with Dr. Wang that portions of the parasternal long-axis view were unavailable, but he concluded that mild or greater aortic regurgitation was visible in certain parasternal long-axis views. In addition, he stated that Dr. Wang's conclusion that the apical views demonstrated trace regurgitation was "incorrect" because several "specific frames"

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16. As previously noted, the Settlement Agreement requires that aortic regurgitation be determined in the parasternal long-axis view unless that view is unavailable; if it is unavailable, the apical views may be used to determine the level of aortic regurgitation. See Settlement Agreement § I.22.

showed a JH/LVOTH of at least 10%. Mere disagreement with the auditing cardiologist, however, is not sufficient.

In any event, the Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and determined that it did not demonstrate at least mild aortic regurgitation. First, Dr. Vigilante determined that "[t]he parasternal long-axis view was available and completely interpretable for evaluation." He concluded, however, that "[t]here was no evidence of aortic regurgitation in the parasternal long-axis view at the appropriate Nyquist limit of 71 cm per second." Second, Dr. Vigilante nevertheless reviewed the apical views on claimant's echocardiogram. He determined "only trace aortic regurgitation was obviously present."

With respect to the opinion of Dr. Koppes that claimant's echocardiogram demonstrated at least mild aortic regurgitation in the parasternal long-axis view, Dr. Vigilante observed that the "time frames documented by Dr. Koppes ... referred only to that part of the study during which the Nyquist limit was inappropriately set very low at 33 cm per second." He also concluded that the time frames identified by Dr. Dlabal referred to the apical three- and five-chamber views where "there was obviously trace aortic regurgitation."[17]

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17. For these reasons, we reject claimant's argument that Dr. Vigilante did not apply the reasonable medical basis standard to the representations made by Dr. Dlabal and Dr. Koppes in support of Mr. Holleyhead's claim and that Dr. Vigilante did not consider the time frames identified by Dr. Dlabal and Dr. Koppes

(continued...)

Finally, we do not agree that claimant is entitled to Matrix Benefits under the Seventh Amendment. As an initial matter, the Seventh Amendment specifically states, "The determinations and actions of the Trust on any aspect of a claim for Cash/Medical Services Benefits of a Category One Class Member or Category Two Class Member, or on any claim for the Matrix Election Payment, shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of claims for Seventh Amendment Matrix Compensation Benefits."[18] Seventh Amendment § IX.E. The Seventh Amendment further provides that:

> For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2 of the Settlement Agreement ....

Id. § IX.A.2. (emphasis added). Section IV.B.1.a. of the Settlement Agreement sets forth:

> 1. .... The following Class Members, and only such Class Members, shall be entitled to the compensation benefits

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17. (...continued)
in their respective declarations.

18. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. Mr. Holleyhead is a Category Two Class Member, and his claim for Level III Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.

> from Fund B ("Matrix Compensation Benefits"):
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> a. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive[19] ... by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period ....

As claimant has not established a reasonable medical basis for finding that he had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period, the Settlement Agreement requires that his claim be denied.

Therefore, we will affirm the Trust's denial of Mr. Holleyhead's claim for Matrix B-1, Level III benefits.

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19. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve." Settlement Agreement § I.22.a.